

§ 331.15

(2) A current list of all individuals with access to agents or toxins listed in § 331.3;

(3) Training records for individuals with access to such agents or toxins;

(4) Accurate and current inventory records (including source and characterization data);

(5) Permits and transfer documents (APHIS Form 2041) issued by APHIS;

(6) Security records (*e.g.*, transactions from automated access control systems, testing and maintenance of security systems, visitor logs); and

(7) Containment and security incident reports.

(b) The responsible official must maintain such records for 3 years.

(c) All records must be produced upon request to APHIS inspectors, and appropriate Federal, State, or local law enforcement authorities.

§ 331.15 Inspections.

(a) To ensure compliance with the regulations, any APHIS inspector must be allowed, without previous notification, to enter and inspect the entire premises, all materials and equipment, and all records required to be maintained by this part.

(b) Prior to issuing a certificate of registration to an entity or individual, APHIS may inspect and evaluate their premises and records to ensure compliance with the regulations and the containment and security requirements.

§ 331.16 Notification in the event of theft, loss, or release of a biological agent or toxin.

(a) The responsible official must orally notify APHIS and appropriate Federal, State, or local law enforcement agencies immediately upon discovery of the theft or loss of agents or toxins listed in § 331.3. The oral notification must be followed by a written report (APHIS Form 2043) within 7 days.

(b) The responsible official must orally notify APHIS immediately upon discovery that a release of an agent or toxin has occurred outside of the bio-containment area. The oral notification must be followed by a written report (APHIS Form 2043) within 7 days. Upon notification and a finding that the release poses a threat to animal or plant health, or animal or plant prod-

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ucts, APHIS will notify relevant Federal, State, and local authorities, and the public, if necessary.

(c) The responsible official must orally notify APHIS of a theft, loss, or release of an agent or toxin by calling (301) 734-5519. A copy of APHIS Form 2043 may be obtained by writing to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236, or by calling (301) 734-5519. APHIS Form 2043 may be mailed to the same address or faxed to (301) 734-8700.

§ 331.17 Administrative review.

An individual or entity may appeal a denial or revocation of registration under this part. An individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins under this part may appeal that decision.¹² The appeal must be in writing and submitted to the Administrator within 30 days of the decision. The appeal must state all of the facts and reasons upon which the individual or entity disagrees with the decision. Where the denial or revocation of registration or the denial or limitation of an individual's access approval is based solely upon an identification by the Attorney General, APHIS will forward the request for review to the Attorney General. The Administrator's decision constitutes final agency action.

PART 340—INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS

Sec.

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AUTHORITY: 7 U.S.C. 1622n and 7701-7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 52 FR 22908, June 16, 1987, unless otherwise noted.

§ 340.0 Restrictions on the introduction of regulated articles.

(a) No person shall introduce any regulated article unless the Administrator is:

(1) Notified of the introduction in accordance with § 340.3, or such introduction is authorized by permit in accordance with § 340.4, or such introduction is conditionally exempt from permit requirements under § 340.2(b); and

(2) Such introduction is in conformity with all other applicable restrictions in this part.¹

(b) Any regulated article introduced not in compliance with the requirements of this part shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests.²

[52 FR 22908, June 16, 1987, as amended at 58 FR 17056, Mar. 31, 1993; 62 FR 23956, May 2, 1997; 66 FR 21058, Apr. 27, 2001]

¹Part 340 regulates, among other things, the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests. The introduction into the United States of such articles also may be subject to other regulations promulgated under the Plant Protection Act (7 U.S.C. 7701-7772) and found in 7 CFR parts 319, 330, and 360. For example, under regulations promulgated in "Subpart-Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Plant Products" (7 CFR 319.37-3), a permit is required for the importation of certain classes of nursery stock whether such stock is genetically engineered or not. Accordingly, individuals should refer to those regulations before importing any nursery stock.

²An inspector may hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of plants, plant

§ 340.1 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been or may be delegated to act in the Administrator's stead.

Animal and Plant Health Inspection Service (APHIS). An agency of the United States Department of Agriculture.

Antecedent organism. An organism that has already been the subject of a determination of nonregulated status by APHIS under § 340.6, and that is used as a reference for comparison to the regulated article under consideration under these regulations.

Courtesy permit. A written permit issued by the Administrator, in accordance with § 340.4(h).

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism.

Environment. All the land, air, and water; and all living organisms in association with land, air and water.

Expression vector. A cloning vector designed so that a coding sequence inserted at a particular site will be transcribed and translated into protein.

Genetic engineering. The genetic modification of organisms by recombinant DNA techniques.

Inspector. Any employee of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or other person, authorized by the Administrator, in accordance with law to enforce the provisions of this part.

Interstate. From any State into or through any other State.

Introduce or introduction. To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

pests, or other articles in accordance with sections 411, 412, 421, and 434 of the Plant Protection Act (7 U.S.C. 7711, 7712, 7731, and 7754).